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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,849	05/22/2001	Sudhir Paul	UNMC 63123DIV	9441

110 7590 02/19/2003

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/862,849

Applicant(s)

PAUL ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 7 and 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 8, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Applicant's election without traverse of claims 6, 8 and 12-13 in Paper No. 7 is acknowledged. Claims 1-5, 7 and 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

The disclosure is objected to because of the following informalities:

The abbreviations "Ab" and "Ag" are used in the instant specification without definition. Abbreviations that are not universally known should be identified in at least the first instant in which they appear, such as page 1, line 20 and page 2, line 11. Apparently the two abbreviations stand for antibody and antigen, respectively.

In the description of Figure 1 on page 8, ΔG_{TS} is referred to but this notation is not seen in Figure 1. Also in Figure 1 ΔG_{rs} and ΔG_f are present but are undefined on page 8.

Appropriate correction is required.

Claims 6, 8 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite in the recitation of "covalently reactive antigen analog". The term is not defined in the claim and would appear on the surface to mean that a reactive antigen analog is covalently bound to something. Since the antigen cannot be bound to the catalytic antibody and still produce a free, active antibody it is taken to mean that something is bound covalently to an antigen with a reactive analog.

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Claim 8 is indefinite in the recitation of "said CRAA". The abbreviation CRAA has not been defined in a prior pending claim and there is no antecedent basis for this term either in the preceding part of claim 8 or in claim 6.

Claim 12 is incorrect in the recitation of "adminstering" on line 3 and "catalytic antibodies" in line 9, which apparently should be "administering" and "catalytic antibodies", respectively.

Claim 13 is indefinite in the recitation of "CRAA" in lines 3 and 5. This abbreviation is not defined in any of the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 8 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a combination written description and enablement rejection.

The instant specification discusses preparing catalytic antibodies to what is termed "catalytic reactive antigen analogs" or CRAAs but not a single antibody was ever apparently made or tested for catalytic activity. Page 7, line 26 through page 81, line 25 discusses naturally occurring catalytic antibodies that cleave gp120, but these catalytic antibodies were not made ac-

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cording to the instant claims but rather were isolated from patients with disease conditions. Furthermore the term "catalytic reactive antigen analog" is confusing and indefinite, as discussed *supra* in the 35 USC § 112 second paragraph rejection. The CRAA to be used for cleaving gp120 is apparently the middle structure in Figure 10 and consists of 11 N-terminal amino acids, a Lys, a phosphonate phenyl ester and 4 amino C-terminal acids. Although the claims are not limited to this specific CRAA, even this structure has not been used as an antigen to make antibodies and these antibodies tested to see if they are catalytic.

In contrast to the production of antibodies that are not catalytic, the production of catalytic antibodies is very unpredictable. The most important thing is choosing the correct antigen. Some antigens will make catalytic antibodies and other will not. Given that the instant specification does not teach the production of any catalytic antibodies it is maintained that one skilled in the relevant art would not believe that applicants had possession of the claimed invention at the time the application was filed. Furthermore, given the unpredictability of producing catalytic antibodies the instant specification does not enable one of skill in the art how to make and/or use the claimed invention. One of skill in the art would not know what particular antigen would produce a catalytic antibody that would act on what particular substrate.

Claim 13 is drawn to a method of "actively immunizing a patient against a microbial infection" by administering, at least twice, a immunogenic microbial epitope from an infectious organism along with an adjuvant and assessing the presence of catalytic antibodies in the serum of the patient. To start with there is no teaching in the instant specification that would make one of ordinary skill in the art believe that active immunization had been produced

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and there is no specific enablement teaching how to produce such a immunization. Such an active immunization requires that the patient remain immunized and that has not been shown. Secondly, it has not been shown in the instant specification that when "an immunogenic microbial epitope from an infectious organism" along with an adjuvant is administered to a patient, a catalytic antibody would be produced.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner, et al. (U). As discussed *supra*, the meaning of "covalently reactive antigen analog" is not defined in the claims and is unclear. Therefore it is taken to mean that something is bound covalently to an antigen with a reactive analog. The instant reference teaches the use of several antigen having analogs to the substrate to produce catalytic antibodies. It would have been obvious to one of ordinary skill in the art to administer the antigens to a test subject with the anticipation that catalytic antibodies would be produced. It would be further obvious to administer transition state analogs with the CRAA. The transition state analog could be the same as a "CRAA" within the definition *supra* or some other transition state analog from the instant reference could have been administered. A copy of this reference is not being sent because it is listed in the instant application.

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Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over either of Blackburn, et al. (V) or Landry (A). Blackburn, et al. teaches medical uses for catalytic antibodies and in the second full paragraph on page 2011 discusses two medical targets for the catalytic antibodies. Landry teaches the production of catalytic antibodies against cocaine and discusses using it in a patient to treat cocaine addiction and overdoses. It would have been obvious to one of ordinary skill in the art to administer the catalytic antibodies taught by the instant references to a patient, absent unexpected results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
February 11, 2003